

REMARKS

Claims 2-5 and 7, and 9-34 are pending in the application. Claims 9, 16, 17, and 26 are independent claims.

Claims 2-5, 7, 9-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

The rejection proffers that claims 9, 16, 17, and 26 are rendered indefinite since it is unclear whether the edge of "...sample application opening defined by at least on edge..." is the same as edges of "...cover having a surface and first and second opposite edges..." For clarification purposes, claims 9, 16, 17, and 26 are amended to replace the term "edge" with the synonym term "border". Support for the amendment is found in the application as filed and particularly in the figures. No new matter is added by virtue of the amendment.

In light of the amendments, the claims are believed to be definite for purposes of 35 U.S.C. 112, second paragraph. Claims 2-5, 7, and 10-15 depend from amended claim 9, claims 18-25 depend from amended claim 17, and claim 27-34 depend from amended claim 26.

The rejection further proffers that claims 3, 20, and 29 are rendered indefinite since it is unclear on what structure the notches are staggered on opposite sides. Each of claims 3, 20, and 29 has been amended to recite that the device includes at least two notches staggered on opposite sides of the border of the sample application opening. Support for the amendment is found in the specification at page 13 line 2 and the claims as originally filed. No new matter is added by virtue of the claim amendments.

In light of the above amendments, reconsideration of the rejection leading to its withdrawal is respectfully requested.

Claims 4, 5, 9-14, 16-18, 21, 22, 24-26, 27, 30, 31, 33, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,843,691 to Douglas et al.

Douglas discloses a reagent test strip that has a porous matrix that incorporates a testing reagent that undergoes a color change in response to the analyte in a biological fluid sample that is applied to the strip. As shown in Figure 3, the test strip has a top layer (36) supporting the matrix/membrane (10). Fingers of an intermediate layer (24) extend between bibulous areas (6,7,8) of the matrix/membrane (10) and a bottom layer (26) is positioned upon the intermediate layer (24).

Claims 9, 16, and 17 are each amended to clarify that the cover has a surface facing the carrier. Further, claims 9 and 16 are each amended to require that the second edge of the cover face the first end of the detection element. Claim 26 is amended to require that its cover has a surface that faces the carrier and that cooperates with a surface of the carrier to form a capillary-active channel. Support for the amendments is found in the specification and figures and particularly figures 1-1G. No new matter is added by virtue of the claim amendments.

It is submitted that Douglas fails to disclose or suggest the device as recited by amended claims 9, 16, and 17 for at least the reasons set forth below. First, Douglas fails to disclose or suggest that a surface of its intermediate layer (24) faces the bottom layer (26) and cooperates with the bottom layer (26) to form the channel (32). The Examiner's attention is directed to Figures 2 and 3 of Douglas where it is illustrated that channel (32) is formed between a surface of the matrix/membrane (10) that faces the bottom layer (26) and that layer (26). The surface of the intermediate layer (24) that faces the layer (26), does not serve to form any portion of the channel (32), but instead supports the layer (26). At most, Douglas teaches an adhesive layer (24a) being positioned between layers (24, 26).

Second, Douglas fails to disclose or suggest that its intermediate layer (24) has opposite first and second edges, wherein the second edge faces the first end of the matrix/membrane (10). The rejection proffers that the first and second ends of the matrix/membrane (10) are defined by the intersection between the matrix/membrane (10) and intermediate absorbent layers (20,22) respectively. See, page 3, paragraph 5 of the Office Action mailed June 23, 2004. This placement is clearly shown by hatched marks (A, B) in Figure 2, and described at Column 12, lines 30-37. Importantly, the intermediate layer (24), extends the length of the test element. See, Figure 2. As such, it lacks an edge that faces the first end of the matrix/membrane (10).

Accordingly, there is simply no disclosure or suggestion in Douglas of a device comprising "a carrier, a detection element having opposite first and second ends, and a cover having a surface facing the carrier and first and second opposite edges, the second edge facing the first end of the detection element, the cover cooperating with a surface of the carrier and with the detection element to form a capillary-active channel, the channel having a sample application opening defined by at least one border, the channel extending at least from the opening to the second end

of the detection element, and wherein at least one notch in the form of a partial groove and having a width less than that of the channel is positioned at the at least one border of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as recited by amended claim 9.

Further, there is simply no disclosure or suggestion in Douglas of a method for withdrawing a liquid sample into an analytical element, the method comprising the steps of "providing a device that comprises a carrier, a detection element having opposite first and second ends, and a cover having a surface facing the carrier and opposite first and second edges, the second edge facing the first end of the detection element, the cover cooperating with a surface of the carrier and the detection element to form a capillary-active channel having a sample application opening defined by at least one border, the channel extending at least from the opening to the second end of the detection element, and wherein at least one notch in the form of a partial groove and having a width less than that of the channel is positioned at the at least one border of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface opposite to the at least one notch facing the channel is exposed and contacting the border of the sample application opening adjacent to the notch with the liquid sample so that the liquid sample is transported by capillary forces into the channel", as recited by amended claim 16.

Still further, there is no disclosure or suggestion in Douglas of a device comprising "a carrier, a detection element having a reagent-impregnated membrane with opposite first and second ends, and a cover having a surface facing the carrier and opposite first and second edges, the second edge facing the first end of the detection element, and the cover cooperating with a surface of the carrier and the detection element to form a capillary-active channel, the channel having a sample application opening defined by at least one border and extending at least from the opening to the second end of the membrane, and wherein at least one notch in the form of a partial groove is positioned at the at least one edge of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface facing

the channel opposite to the at least one notch is exposed", as recited by amended claim 17.

As such, claims 9, 16 and 17 as amended are not anticipated and are believed to be patentable over Douglas. Claims 4, 5, and 10-14 depend from amended claim 9. Claims 18, 21, 22, and 24 depend from amended claim 17.

It is submitted that Douglas fails to disclose or suggest the device as recited by amended claim 26 for at least the reason set forth below. The Examiner's attention is directed again to Figures 2 and 3 of Douglas where it is illustrated that the intermediate layer (24) fails to possess a surface that faces the bottom layer (26) and that cooperates with the bottom layer (26) to form the channel (32). As best shown in Figure 3, the surface of the layer (24) that faces the layer (26), itself supports the layer (26). At most, Douglas teaches an adhesive layer 24a being positioned between layers (24, 26). Channel (32) is instead formed between a surface of the matrix/membrane (10) that faces the bottom layer (26) and that layer (26).

Accordingly, there is no description or suggestion in Douglas of a device comprising "a carrier, and a cover having a surface that faces the carrier and that cooperates with a surface of the carrier to form a capillary-active channel, the channel having a sample application opening defined by at least one border and wherein at least one notch in the form of a partial groove and having a width less than the channel's width is positioned at the at least one border of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as recited by amended claim 26. As such, claim 26 as amended is not anticipated and is believed to be patentable over Douglas. Claims 27-34 depend from claim 26.

It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 102(b). Entry of the amendments leading to reconsideration of the rejection of the claims and withdrawal of the rejection is respectfully requested.

Claims 2-5, 9, 11-14, 16, 17, 19-22, 24-26, 28-31, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0138152 to Lilja. The rejection is respectfully traversed.

Lilja discloses a disposable cuvette for sampling a fluid and analyzing the sample. The cuvette includes a body wall (10) that defines a cavities (25, 25') and a channel (26) that directly ends at its edge.

Claims 9, 16, and 17 are amended to clarify the relative structure between the carrier, the detection element, and the cover. Specifically, claims 9, 16, and 17 each recite that the cover has a surface facing the carrier and first and second opposite edges, the second edge facing the first end of the detection element. Support for the amendment is found in the specification as filed and particularly Figures 1A-1G.

It is submitted that the resulting modification proffered by the rejection fails to show or suggest a device as recited in claims 9, 16, and 17 in light of the amendments and/or the accompanying remarks.

Differences between the claimed device and method and the cuvette of Lilja exist by Lilja's teaching of its body wall (11) of semipermeable membrane material. Lilja at most teaches that its body wall (11) extends across the cavity (12) and rests upon the body wall (10). Such structure is in direct contrast to the devices recited in claims 9, 16, and 17 respectively. Claims 9, 16, and 17 each recite that the cover has surface facing the carrier and opposite first and second edges, wherein the second edge faces the detection element. Not one of the figures of Lilja discloses an edge of a cover facing a detection element. In fact, as shown in Figure 1, the edges of the body wall (11) form the edges of the cuvette.

Additionally, the Examiner's statement at page 6 of the Office Action mailed June 23, 2004, that "Lilja does not disclose one of the cover or carrier without notches and the other with notches, such that one side of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", is acknowledged. Lilja at most discloses an opening to the channel (26) at an edge where the capillary gap ends and which is necessarily parallel to that channel (26) and thus the direction of spread of the liquid sample.

In order to highlight the differences between the claimed device of claims 9, 16, 17, and 26 and the cuvette of Lilja, the Examiner's attention is first directed to Figure 1 of Lilja where the opening end of the channel (26) is illustrated. It is noted that the application of a sample to the capillary (26) is at an edge where the capillary gap ends and which is necessarily parallel to that channel (26) and thus the direction of spread of the liquid sample. This configuration was recognized by Applicants to

create frequent problems. In that regard, Applicants taught in the specification at page 3, second paragraph that one frequent problem with such a configuration is that "liquid drops which are applied to the sample application opening of the capillary gap are not able to penetrate into the gap".

Applicant's ignored Lilja's teaching of the capillary (26) at the edge and taught instead in the specification that "the notch in a surface forming the capillary channel . . . serves to ensure that the sample liquid can enter into the capillary channel. This is achieved in that the sample drop can be directly applied to one of the surfaces, whose extension forms the inner surface of the capillary". See, page 4 last paragraph to page 5 line 4. Lilja's capillary opening does not provide this assurance of sample entry into the capillary channel (26).

The modification of Lilja cannot be motivated by hindsight in view of Applicant's specification. There is no motivation in the cited reference to modify the body wall (11) that extends over cavity (12) as taught by Lilja to meet the requirements of the cover as defined by claims 9, 16, 17, and 26. Further, there is no motivation or suggestion in Lilja to modify the opening of its channel (26).

In light of the above, it is submitted that Lilja, when taken as a whole, fails to disclose or suggest a device comprising "a carrier, a detection element having opposite first and second ends, and a cover having a surface facing the carrier and first and second opposite edges, the second edge facing the first end of the detection element, the cover cooperating with a surface of the carrier and with the detection element to form a capillary-active channel, the channel having a sample application opening defined by at least one border, the channel extending at least from the opening to the second end of the detection element, and wherein at least one notch in the form of a partial groove and having a width less than that of the channel is positioned at the at least one border of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as required by amended claim 9. Claims 2-5 and 11-14 depend from amended claim 9.

It is further submitted that in light of the above, that Lilja when taken as a whole fails to disclose or suggest a method comprising the steps of "providing a device that comprises a carrier, a detection element having opposite first and second ends, and a cover having a surface facing the carrier and opposite first and second

edges, the second edge facing the detection element, the cover cooperating with a surface of the carrier and the detection element to form a capillary-active channel having a sample application opening defined by at least one border, the channel extending at least from the opening to the second end of the detection element, and wherein at least one notch in the form of a partial groove and having a width less than that of the channel is positioned at the at least one border of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface opposite to the at least one notch facing the channel is exposed and contacting the border of the sample application opening adjacent to the notch with the liquid sample so that the liquid sample is transported by capillary forces into the channel", as required by amended claim 16.

Still further, it is submitted that in light of the above, that Lilja when taken as a whole fails to disclose or suggest a device that comprises "a carrier, a detection element having a reagent-impregnated membrane with opposite first and second ends, and a cover having a surface facing the carrier and opposite first and second edges, the second edge facing the first end of the detection element, and the cover cooperating with a surface of the carrier and the detection element to form a capillary-active channel, the channel having a sample application opening defined by at least one border and extending at least from the opening to the second end of the membrane, and wherein at least one notch in the form of a partial groove is positioned at the at least one edge of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as required by amended claim 17. Claims 19-22 and 24-25 depend from amended claim 17.

In light of the above, it is submitted that Lilja when taken as a whole fails to disclose or suggest a device comprising "a carrier, and a cover having a surface that faces the carrier and that cooperates with a surface of the carrier to form a capillary-active channel, the channel having a sample application opening defined by at least one border and wherein at least one notch in the form of a partial groove and having a width less than the channel's width is positioned at the at least one border of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch

and the surface facing the channel opposite to the at least one notch is exposed” ”, as required by amended claim 26. Claims 28-31, 33, and 34 depend from amended claim 26.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Entry of the amendments, reconsideration of the rejections of the claims, and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claims 2-5, 9, 11-14, 16, 17, 19-22, 24-26, 28-31, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0138152 to Lilja in view of U.S. Patent No. 5,942,102 to Hodges. Lilja has been discussed above with reference to amended claims 9, 16, 17, 26.

It is respectfully submitted that the secondary reference to Hodges et al. fails to cure the above-stated inadequacies of Lilja.

Regarding claims 9, 16, and 26, Hodges et al. is devoid of description or suggestion of a device comprising a notch having a width less than that of the channel that is positioned at the at least one edge of the sample application opening of the channel. Hodges et al. at most discloses a cell having a wall 10 that notched at 9 to provide a solution to be admitted to the cell or to be drawn in by wicking or capillary action and to allow air to escape. (Column 5, lines 3-6). It is these notches (9), which form the path to the cell. Again, such a configuration was recognized by Applicants to create frequent problems. As discussed above, Applicants taught in the specification at page 3, second paragraph that one frequent problem with such a configuration is that “liquid drops which are applied to the sample application opening of the capillary gap are not able to penetrate into the gap”.

Applicant's ignored Hodges's teaching of a notch (9) at the edge and taught instead in the specification that “the notch in a surface forming the capillary channel . . . serves to ensure that the sample liquid can enter into the capillary channel. This is achieved in that the sample drop can be directly applied to one of the surfaces, whose extension forms the inner surface of the capillary”. See; page 4 last paragraph to page 5 line 4. The mere presence of Hodges' notch (9) does not provide this assurance of sample entry into the notch (9).

Further, Hodges et al. is devoid of description or suggestion of a device comprising a carrier, a detection element having opposite first and second ends, and a cover having a surface facing the carrier and first and second opposite edges, the second edge facing the first end of the detection element. Hodges et al. at most discloses a core (4) having a polyester sheet (1) adhered to one side and a second polyester sheet (7) adhered to the other side. See, Figure 10. Hodges et al. is silent as to the existence of such a configuration. As such, Hodges et al. fails to cure the inadequacies of Lilja.

In light of the above, it is submitted that Lilja and Hodges et al. when taken as a whole, fail either alone or in combination to disclose or suggest a device recited in claims 9 and 26 or the method of claim 16. Claims 2-5 and 11-14 depend from amended claim 9. Claims 28-31, 33, and 34 depend from amended claim 26.

Regarding claim 17, Hodges et al. is devoid of description or suggestion of a device comprising a carrier, a detection element having a reagent-impregnated membrane with opposite first and second ends, and a cover having a surface facing the carrier and opposite first and second edges, the second edge facing the first end of the detection element. Hodges et al. at most discloses a core (4) having a polyester sheet (1) adhered to one side and a second polyester sheet (7) adhered to the other side. See, Figure 10. Hodges is silent as to the existence of such a configuration.

Further, Hodges et al. is devoid of description or suggestion of the claimed notch positioned at the at least one edge of the sample application opening of the channel so that the surface facing the channel opposite to the at least one notch is exposed. As such, Hodges et al. fails to cure the inadequacies of Lilja. In light of the above, it is submitted that Lilja and Hodges et al. when taken as a whole, fail either alone or in combination to disclose or suggest a device recited in claim 17. Claims 19-22, and 24-25 depend from amended claim 17.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejections of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claims 2-5, 9, 11-14, 16, 17, 19-22, 24-26, 28-31, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable U.S. Patent No. 5,942,102 to Hodges et al.

Hodges et al. has been discussed above with reference to amended claims 9, 16, 17, 26. Claims 2-5 and 11-14 depend from amended claim 9, claims 19-22 and 24-25 depend from amended claim 17, and claims 28-31, 33, and 34 depend from amended claim 26.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejections of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claims 2, 3, 19, 20, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable U.S. Patent No. 5,843,691 to Douglas et al. in view of U.S. Patent No. 4,439,526 to Columbus or U.S. Patent No. 5,942,102 to Hodges et al. or EP 0138152 to Lilja. Claims 9, 17, and 26 have been discussed above with reference to Douglas et al., Hodges et al., and Lilja.

Columbus et al. discloses a device having an exterior surface for receipt of liquid deposited and a wall means interior of the surface for transporting liquid by capillary attraction along a passage. See, Column 2, lines 29-33. Columbus fails to cure the inadequacies of Douglas et al., Hodges et al. and Lilja in relation to amended claims 9, 17, and claim 26. Claims 2-3 depend from claim 9, claims 19-20 depend from claim 17, and claims 28-29 depend from claim 26.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejections of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claims 7, 15, 23, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable U.S. Patent No. 5,843,691 to Douglas et al. or EP 0138152 to Lilja, alternatively in view of U.S. Patent No. 5,942,102 to Hodges et al. in view of U.S. Patent No. 6,238,624 to Heller et al. Claims 9, 17, and 26 have been discussed above with reference to Douglas et al., Lilja, and Hodges et al.

Heller et al. disclose a self-addressable, self-assembling microelectronic device designed and fabricated to actively carry out and control multi-step and


multiplex molecular biological reactions in microscopic formats. See, the abstract. Heller et al. fail to cure the inadequacies of Douglas et al., Lilja, and Hodges et al. in relation to amended claims 9, 17, and 26. Claims 7 and 15 depend from amended claim 9 and, claim 23 depends from amended claim 17, and claim 32 depends from amended claim 26.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejections of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

This application is deemed to be in condition for allowance and as such is respectfully requested. In addition, if necessary, it is requested that this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and fees be charged to Deposit Account No. 50-0877 (with reference to RDID 0043 US).

Respectfully submitted,

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